

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: GRUNDLER, Christoph

SERIAL NO.: 10/531,058

ART UNIT: 4177

FILED: January 17, 2006

EXAMINER: Stuart, C. W.

TITLE: DEVICE AND METHOD FOR TEMPERING AND HUMIDIFYING GAS,
ESPECIALLY RESPIRATORY AIR

Amendment E: REMARKS

Upon entry of the present amendments, previous Claims 25 and 26 have been canceled and new Claims 27 and 28 substituted therefor. Reconsideration of the rejections, in light of the foregoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of further distinguishing the present invention from the prior art combination.

In the Office Action, it was indicated that Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Dobritz patent in view of the Jackson patent and the Stueble patent.

As an overview to the present reply, Applicant has revised previous independent Claim 25 in the form of new independent Claim 27. New independent Claim 27 now specifies, in the preamble, that the gas is for "direct" delivery to the patient. It is further indicated that the filling material "extends substantially entirely across an interior of said humidification chamber". The gas is saturated with fluid "at between 95% and 100% humidity". Additionally, and furthermore, it is now indicated that the "heating means" serves to elevate the temperature of the fluid in the fluid reservoir to a body temperature of approximately 37°C. Applicant respectfully contends that these limitations

are neither shown nor suggested by the prior art combination of the Dobritz, Jackson and Stueble patents.

With respect to the Dobritz patent, Applicant respectfully disagrees with the Examiner's analysis. Fundamentally, the Dobritz patent does not show a humidification chamber having a filling material. In particular, as can be seen in column 12, line 20 through column 4, line 7 of the Dobritz patent, the Dobritz patent provides a breathing air humidifier having a receptacle 5 which defines an annular water chamber 5a. The water chamber 5a is maintained filled with water. This water chamber 5a is separated from an interior passage 6a for the inspired air by means of a foil material 6. In the Dobritz patent, this foil material is made such that it will be impervious to water but pervious to water vapor.

Applicant respectfully contends that the foil material 6 that forms the passage 6a is comparable to the filling material of the present invention. In particular, so as to further distinguish the present invention from the Dobritz patent, it is now recited that the filling material extends "substantially entirely across" an interior of the humidification chamber. In this case, the foil material 6 in the Dobritz patent simply extends longitudinally along the length of the humidifier. As such, there would be no "filler material" that extends "substantially entirely across an interior of the humidification chamber".

Applicant notes that the apparatus of the Dobritz patent is comparable to the devices that were discussed in paragraph [0022] of the original filed Applicant. In particular, paragraph [0022] reads as follows:

Partially permeable hollow fibers (e.g. from PTFE) are bundled, and the gas to be heated and humidified is directed through their luminae. The outer surface of the fibers is in contact with the

fluid needed for humidification. The disadvantage of that design is the fibers' limited life-time and mechanical as well as thermal durability. Moreover, the fibers' unsuitably high thermal resistance unduly restricts the heat transfer needed to compensate for evaporation coldness. Thus especially with high gas flow the heating of the gas is insufficient, which in turn leads to insufficient gas humidification. From theory increasing the water's temperature might compensate for those limitations. In case of a heavily varying gas flow, however, even forced heating of the fibers will not lead to constant humidification due to technical limitations of controlling the instantaneous fibre temperature as fast as required.

As such, the use of the Dobritz patent will result in heavily varying gas flows. As such, during high volumes of gas flow, a very limited humidification would occur to the gases passing through the interior passage 6a. In the Dobritz patent, it is not possible to control the temperature and humidity of the passing air easily by means of the drive device and the temperature control heating circuitry 11 provided therein. In the present invention, control of temperature and humidity occurs in a unique fashion. This was recited in paragraph [0051] of the original specification as follows:

There is no aerosol formation. Instead the gas is saturated with molecular fluid. It is of special significance that both temperature and humidity are easily controlled by means of the drive and the temperature-controlled heating circuitry.

Fundamentally, the Dobritz patent would lack the limitations of the present invention as defined by independent Claim 27 herein. The Dobritz patent does not describe a system for heating and humidifying a gas for "direct" delivery to a patient. The Dobritz patent lacks the "filling material extending substantially entirely across an interior of said humidification chamber". The configuration of the foil material and the water would not allow the fluid to be moved through the gas so as to saturate the gas with fluid "at between 95% and 100% humidity". Additionally, and furthermore, there is no indication that the heating means serves to elevate the temperature of the

fluid in the fluid reservoir to a temperature "of approximately 37°C".

The limitations with respect to humidity and temperature find their antecedent bases from the original specification. The basis of the "37°C" is found in paragraph [0094] of the original specification. Paragraph [0014] indicates that the gas will have "a saturation of 95 to 100% relative humidity".

The combination of the Dobritz patent with the Jackson patent would not be obvious to one having ordinary skill in the art and, fundamentally, would not make very much sense. This combination would result in providing the filling material in the humidification chamber as well as a distribution chamber with a sieve bottom (according to the Jackson patent) as well as a separate interior passage 6a for inspirited air made of a foil material 6 (according to the Dobritz patent). Such a construction would have filling material on the outside of the foil material 6 of the Dobritz patent, but not water. As a result, this would cause even worse humidification of any gas streaming through the interior passage 6a. Accordingly, the combination of the Dobritz patent and the Jackson patent would not result in the present invention, as defined by independent Claim 27 herein.

Applicant respectfully disagrees that one having ordinary skill in the art would combine the Dobritz patent with the Jackson patent and the Stueble patent. The Stueble patent deals with an air conditioning process and device to condition air that has been removed from and routed back to a room, respectively. Fundamentally, the air conditioning device proposed by the Stueble patent is from a field of art quite removed from that of the present invention. Such an air conditioning device would not be comparable, in any way, to a respiratory gas flow generator, in the nature of the present invention. Fundamentally, a respiratory gas flow generator has to be able to react to an instantaneous respiratory gas flow that may vary widely during a single respiratory cycle. One having ordinary

skill in the art would easily understand that during such a respiratory cycle, the patient must breath in and breath out. As such, it must be ensured that the gas which is exhaled by the patient is not breathed in again by the patient. As such, the gas flow during the respiratory cycle would have to have sinusoidal changes. At the same time, the gas flow chamber has to be able to provide a slightly raised pressure to effect the inhalation of a patient and to shortly thereafter lower pressure so as to effect an exhalation of a patient. This will occur during artificial respiration. This is quite different than the notion of the air conditioning of a room. The air conditioning of a room would not have a continuous change of flow direction nor a continuous change of pressure that has to be dealt with. One having ordinary skill in the art would not look to the technology associated with room air conditioners in order to achieve the structure, functions and advantages of the present invention. As such, Applicant respectfully contends that the combination of the Dobritz and Jackson patents would not be considered to be "obvious" with the combination of the Stueble patent. It is unlikely that anyone would actually look to the art of room air conditioners for the purposes of creating a better system for heating and humidifying a gas for "direct" delivery to a patient.

So as to more clearly distinguish the present invention from room air conditioners, such as shown by the Stueble patent, independent Claim 27 specifically recites that the gas is heated to about body temperature and humidified to nearly full saturation. Fundamentally, room air conditioners would never be intended to deliver gas to a patient at about body temperature nor at full saturation. On this basis, Applicant contends that independent Claim 27 is different in structure, function and in results achieved from that of the prior art combination.

Dependent Claim 28 corresponds to the limitations of previous dependent Claim 26.

Based upon the foregoing analysis, Applicant contends that independent Claim 127 is now

in proper condition for allowance. Additionally, that claim which are dependent upon independent Claim 27 should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

March 11, 2011
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